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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,837	02/13/2007	Chikao Morimoto	2144.0150002/RWE/RAS	8525

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
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1635

MAIL DATE	DELIVERY MODE
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06/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,837	Applicant(s) MORIMOTO ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,3-11 and 13-35 is/are pending in the application.
- 4a) Of the above claim(s) 5, 13-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 03/24/2009 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 12/24/2008 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 03/24/2009, claims 1, 3-11 and 13-35 are pending in the application. Claims 1, 3, 4 and 6-11 are currently under examination

Response to Applicant's Arguments

Re: Claim Rejections - 35 USC § 112

The rejection of claims 1, 3, 4, and 6-11 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the reasons of record.

Applicant's arguments filed 03/24/2009 have been fully considered but they are not persuasive. Applicants have amended claims 1 and 11 by canceling claims 2 and 12 and moving the limitations into claims 1 and 11 and argue that the rejections against claims 2 and 12 were erroneous. Applicants argue that if Examiner's position in stating

Art Unit: 1635

the method was not adequately described, then all methods for screening for new drugs would not be patentable.

This argument is not convincing because the written description rejection was not against the method not being adequately described, it was against the genus of substances that are capable of inhibition and against any interaction between factors in the CD26 signaling pathway. The claim amendments to claim 1 and 11 address the lack of adequate description regarding the breadth of the substance inhibiting any interaction between any factor in the CD26 pathway by limiting the invention to the interaction between CD26 and caveolin-1. As stated in the previous Office action, the instant method embrace and contemplate determining whether *any* substance is capable of inhibiting and the instant specification only describes the use of siRNA to inhibit specific interactions within said pathway.

The instant specification does not describe the entire genus of substances that are capable of inhibiting the claimed interaction between factors in the CD26 signaling pathway. The genus of substances capable of inhibiting the claimed interaction is vast and could encompass antibodies, small molecules, peptides as well as the described siRNA molecule. Description of a siRNA molecule capable of binding to a factor in the CD26 signaling pathway does not provide adequate written description of the infinite number of substances within the genus as instantly claimed. Description of a siRNA molecule does not provide any relevant identifying characteristics of an antibody, for example, and does not provide any relevant functional characteristics of an antibody because siRNA bind to a target nucleic acid sequence to inhibit expression of a factor in

Art Unit: 1635

the CD26 signaling pathway and antibodies do not function by binding to a target nucleic acid sequence. One of skill in the art could not predict the operability in the invention of any species within the claimed genus other than the one adequately described. The skilled artisan would not be able to immediately envisage the substance claimed from the disclosed method.

Therefore, Applicants have not adequately described the invention.

Re: Claim Rejections - 35 USC § 102

The rejection of claims 1, 3, 4, 6, 7 and 8 under 35 U.S.C. 102(a) as being anticipated by Williams et al. (Clin Exp Immunol January 2003) is obviated in view of the claim amendments filed 03/24/2009.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 3-4, 6-12 under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (Clin Exp Immunol January 2003) and Pei et al. (US Patent No. 7, 205,409) is obviated in view of the claim amendments filed 03/24/2009.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1635

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Thursday between 6 and 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service

Art Unit: 1635

center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Primary Examiner
Art Unit 1635